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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,632	02/16/2001	Jin-Soo Kim	12279-002001	3563
26161	7590	06/02/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			MCKELVEY, TERRY ALAN	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/785,632

**Applicant(s)**

KIM ET AL.

**Examiner**

Terry A. McKelvey

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 9/9/02, 10/30/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-35 and 86-119 is/are pending in the application.
- 4a) Of the above claim(s) 24-31, 34, 35, 87, 94 and 99-119 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23, 32, 33, 86, 88-93 and 95-98 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 February 2004 and 16 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/00; 4/02; 12/02</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

#### ***Election/Restrictions***

Applicant's election with traverse of Group I (now joined with Group II), species made by amplifying and joining, test zinc finger identified in a sequence database, and activation domain, now claims 1-23, 32-33, 86, 88-93, and 95-98 in the papers filed 9/9/02 and 10/30/03 is acknowledged. The traversal is on the ground(s) discussed below. This is not found persuasive (concerning the traversal of the restriction between the remaining groups) for the reasons discussed below.

First, upon review of the applicant's arguments concerning the election of species requirements, the applicant's arguments are persuasive and the election of species requirements for the first two species are withdrawn. The other species, drawn to elected activation domain, remains.

Second, the Applicant's conclusion that claims 1-35 and 86-119 will be examined because the Examiner indicated that these claims are pending in the communication mailed 9/26/03 and did not further restrict the claims is incorrect because the election of species requirement clearly indicated that it was based upon the elected Group I/II and thus the previous election

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applies. The elected claims that are under examination are claims 1-23, 32-33, 86, 88-93, and 95-98.

Third, concerning the applicant's traversal of the restriction between different inventions, the traversal is on the grounds that the Applicant while agreeing that the inventions of Groups I, III, and IV are distinct and non-obvious, they are connected in design, and could logically depend from each other and since claim 95 is generic to and links all three groups, it is logical to examine claim 95 and claims dependent therefrom along with Groups I, III, and IV without posing an undue burden. This argument is not persuasive because even if claim 95 is considered to be a linking claim linking all three groups, the presence of a linking claim does not mean that it is not a burden to examine all of the linked groups. As the applicant admits, the three groups are patentably distinct and unobvious from each other. This is essentially agreeing that there are three different inventions. It is an undue burden to examine three different inventions in one application. Linking claim practice will be followed as applicable. However, as shown by the instant action, rejoinder of the linked inventions is not necessary at this time.

The requirement is still deemed proper and is therefore made FINAL.

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Claims 24-31, 34-35, 87, 94, and 99-119 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the papers filed 9/9/02 and 10/30/03.

### ***Specification***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

For example, there is a hyperlink at page 9, line 19. The applicant is required to review the entire application and delete or alter all of the hyperlinks so that they are no longer hyperlinks.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35

U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-23, 32-33, 86, 88-93, 95-98 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to methods of identifying a zinc finger domain that recognizes a target site on a DNA comprising providing a plurality of hybrid nucleic acids, each of which encodes a non-naturally occurring protein. The genus of methods is huge and essentially limitless because the genus is defined by the use of "hybrid nucleic acid molecules" which are only limited by the encoded protein comprising a transcriptional regulatory domain, a DNA binding domain that recognizes a "recruitment site", and a test zinc finger domain, with the proviso that the encoded protein is non-naturally occurring.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical

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properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. All naturally occurring proteins are not even close to being known and described. Because the hybrid nucleic acids are defined as non-naturally occurring, there must be description of all naturally occurring proteins in order to exclude them from the hybrid nucleic acids used in the claims (and thus describe the nucleic acids used in the claims).

There is no description in the specification of even one hybrid nucleic acid which is definitively non-naturally occurring because all of the natural proteins are not known, which natural proteins encompass proteins that result from radical mutations that naturally occur such as chromosomal translocations and breakpoint mutations that fuse reading frames. All of the proteins not previously described which are naturally occurring are simply unpredictable because, for example, such proteins encompass proteins from mutant genes which may naturally fuse together the DNA binding domains of different genes or make proteins that have the same mutated sequence as one or more of the hybrid nucleic acids encoding a supposedly non-naturally occurring protein. Accordingly, in the absence of sufficient recitation of distinguishing characteristics (distinguishing the hybrid nucleic acids which

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encode non-natural proteins from those that encode natural proteins), the specification does not provide adequate written description of the claimed genus which encompasses the second type of inhibitor.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*."

(See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of hybrid nucleic acid molecules that encode non-naturally occurring proteins required by the claimed method, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v.*



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*Revel*, 25USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v.*

*Chugai Pharmaceutical Co. Ltd.*, 18USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, none of the claims drawn to the use of hybrid nucleic acid molecules which encode non-naturally occurring proteins meets the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Regarding claim 16, etc, the use of "when a transcription factor recognizes both a recruitment site and a target site of the promoter, but not when the transcription factor recognizes only the recruitment site of the promoter" in conjunction with the remaining steps renders the claims vague and indefinite because the relationship between the transcription factor and the hybrid nucleic acids made by steps (b)-(c) is unclear. Is the transcription factor made by the hybrid nucleic acids? Or, is it a separate transcription factor and the hybrid nucleic acids produce a separate transcription factor that competes with the transcription factor of step (a)? Amending the claims to clearly indicate whether the hybrid nucleic acids encode the transcription factor or an additional transcription factor would be remedial.

#### **Conclusion**

No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 703-872-9306. NOTE: If Applicant does

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submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (571) 272-0775. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (571) 272-0781.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
TERRY MCKELVEY  
PRIMARY EXAMINER